

Review Article

A review of interspinous fusion devices: High complication, reoperation rates, and costs with poor outcomes

Nancy E. Epstein

Department of Neurological Surgery, The Albert Einstein College of Medicine, Bronx, NY, 10467, and Chief of Neurosurgical Spine and Education, Winthrop University Hospital, Mineola, NY 11501, USA

E-mail: *Nancy E. Epstein - dch3@columbia.edu

*Corresponding author

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Abstract

Background: Interspinous fusion devices (IFDs) are increasingly offered to patients over the age of 50 with lumbar spinal stenosis and intermittent neurogenic claudication. Here, we review the literature on complication rates, reoperation rates, and outcomes for implanting IFD, and offer an assessment of IFD charges at a single institution in 2010.

Methods: The literature concerning IFD implants was reviewed with particular attention focused on complications, reoperation rates, and outcomes. Additionally, the costs of implanting 31 IFD devices in 16 patients at one to three levels at a single institution in 2010 are presented.

Results: Reviewing the spinal literature concerning the postoperative status of IFD followed over an average of 23–42.9 postoperative months revealed that IFD resulted in 11.6–38% complication rate, 4.6–85% reoperation rate, and 66.7–77% frequency of poor outcomes. Additionally, the 31 devices implanted in 16 patients at a single university hospital in 2010 cost a total of \$576,407.

Conclusions: With high maximal complication rates (38%), reoperation rates (85%), poor outcomes (77%), and high costs (\$576,407 for 31 devices in 16 patients), the utilization and implantation of IFD remains extremely controversial and should be investigated further.

Key Words: Complications, high costs, interspinous fusion devices, lumbar stenosis, poor outcomes, reoperations

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INTRODUCTION

Multiple interspinous fusion devices (IFDs), including the X-STOP (Medtronic, Memphis, TN, USA), have been utilized to treat older patients (age 50 and over) with lumbar spinal stenosis and intermittent neurogenic claudication. The Food and Drug Administration (FDA) has approved the implantation of IFD in the lumbar spine at one or two levels. Here, we review the

complication rates, reoperation rates, and outcomes for IFD utilized to treat lumbar stenosis. We also include an assessment of the charges for implanting these devices at a single institution in 2010.

APPROVAL ORDER STATEMENT FOR THE X-STOP IFD DEVICE

The FDA approved the X-STOP IFD (originally St.

Francis Medical Technologies Inc., Alameda, CA, USA) on November 21, 2005 (for Medtronic Spine LLC; P04001) as follows: "Approval for the X-STOP interspinous process decompression system (Internet Site: X-STOP(R) IPD(R) System Risk Management Statement-Medtronic). The device is indicated for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis (with X-ray, MRI, and /or CT evidence of thickened ligamentum flavum, narrowed lateral recess and/or central canal narrowing). The X-STOP is indicated for those patients with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain, and have undergone a regimen of at least 6 months of nonoperative treatment. The X-STOP may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels."

Contraindications to the X-STOP device included "allergy to titanium or titanium alloy, spinal anatomy that prevents implantation due to significant instability, ankylosis, acute fracture of the spinous process or pars interarticularis, significant scoliosis, neural compression causing neurogenic bowel or bladder dysfunction, severe osteoporosis, and active systemic infection at the locale of potential device implantation" (Internet Site: X-STOP(R) IPD(R) System Risk Management Statement-Medtronic).

BIOMECHANICAL TESTING OF THE IFD

IFD devices biomechanically limit extension and increase flexion, thereby enlarging the spinal canal and neural foramina at stenotic levels.^[3,7,11,13] Findings in one cadaveric study (eight cadavers) utilizing four different IFD devices implanted at the L2–L5 levels revealed a marked reduction in flexion/extension but a "higher range of motion during lateral bending and rotation."^[7] A second biomechanical study utilizing the X-STOP (Medtronic) device showed that it "... distracts the posterior elements of adjacent vertebral bodies, unloading the intervertebral disc, limiting spinal extension, and improving central canal and neuroforaminal stenosis."^[3] Third and fourth studies found that over the long term, radiographic improvement in foraminal height, width, and cross-sectional area were either maintained or "regressed" with IFD.^[11,13] In the former study, utilizing the X-STOP device in 39 patients, MR scans performed at two postoperative years documented that canal and foraminal enlargement were maintained and the range of motion was preserved.^[11] However, in that latter series, involving 129 patients utilizing three types of IFD [X-STOP (Medtronic), Wallis (Abbott Spine, Austin, TX, USA) and Diam (Medtronic)], radiographic improvement seemed to revert toward initial values within 202–527

postoperative days.^[13]

Few high-quality studies adequately analyze the safety and efficacy of the X-STOP IFD.^[8] Looking at multiple databases [PubMed, MEDLINE, and Cumulative Index to Nursing and Allied Health Literature (CINHAL)] and utilizing several key words (interspinous implants/devices/spacers, dynamic stabilization, X-STOP, Coflex, Wallis, and Diam), Kabir *et al.* assessed whether implanting IFD devices in patients over the age of 50 with lumbar stenosis improved outcomes when compared with non-operative management.^[8] They found that only two randomized controlled trials utilized the X-STOP device while other studies were of poor quality. They concluded, "... due to the small number and poor design of studies, it is difficult to clearly define indications for their use in lumbar degenerative disease."

COMPLICATIONS, REOPERATION RATES, AND POOR OUTCOMES ATTRIBUTED TO IFD

In six studies involving a total of 384 cases (range 12–175 per study), implanting IFD devices correlated with various complications rates, reoperation rates, and poor outcomes.^[1,3,5,9,10,14] Single-level devices were implanted in 343 cases, while two-level IFDs were placed in 41 cases.^[1,3,5,9,10,14] Patients were followed for an average of 23 months, and up to 4 years.^[1,3,10,14]

Complications of interspinous fusion devices

The overall complication rate for implanting IFD ranged from 11.6 to 38%.^[1,3,5,9,10,14] In the first study, the complication rate for IFD (X-STOP) in 13 patients was 38%.^[3] X-STOP devices were implanted at the L4–L5 (nine patients) and at both the L3–L4 and L4–L5 levels (four patients). Nine patients had severe and four had moderate stenosis. Five of the 13 patients also exhibited grade I degenerative spondylolisthesis. Over an average of 42.9 postoperative months (range 3–48 months), 3 (23%) patients developed symptomatic spinous process fractures largely attributed to over distraction of osteopenic/osteoporotic spinous processes. An additional 2 (15%) patients developed new radicular deficits. The latter complications were attributed to poor patient selection, including placing X-STOP devices in patients with severe stenosis, grade I spondylolisthesis, adjacent level disease, and/or severe foraminal stenosis.

In the second study utilizing 50 IFD devices [34 X-STOP Titanium and 8 X-STOP polyether ether ketone (PEEK; Medtronic), and 8 Lanx Aspen (Lanx, Inc., Broomfield CO, USA)] implanted in 38 patients (26 at L4–L5, and 12 at L3–L4/L4–L5), the frequency of spinous process fractures documented on CT but missed on X-ray was 22% (11 patients).^[9] The failure of X-ray to detect these fractures was attributed both to osteopenic bone and

the observation that the metal in the IFD implants obscured the fractures.^[9] Of interest, only 5 of 11 patients with spinous process fractures were symptomatic and just 3 required device removal with decompressions (laminectomy).

In the third study involving 69 patients treated with the X-STOP (46 one-level and 23 two-level procedures) and followed for an average of 23 months, 8 (11.6%) patients developed device-related complications: 4 device dislocations and 4 spinous process fractures.^[11] In the fourth study (derivative of the third study), three patients, aged 47, 63, and 75, underwent two-level adjacent X-STOP placement (L3–L4/L4–L5 levels); they developed the “sandwich phenomenon” defined as a fracture of the intervening spinous process.^[1,2] Device failure in two of these patients was signaled by recurrent symptoms within 4–6 months of surgery; both L4 spinous process fractures were treated with device removal, decompressions, and fusion. The third patient, who developed recurrent back pain 18 months later, refused additional surgery.

In the fifth study, a case report, an 84-year-old male underwent the initial placement of an X-STOP device at an outside institution at the L4–L5 level. This resulted in an immediate postoperative bilateral foot drop.^[6] Three months later, the device extruded and was removed. Finally, 6 months later, another surgeon performed an L4–L5 laminectomy that resulted in partial resolution of the profound bilateral foot drop.

High reoperation rates attributed to interspinous fusion devices

Reoperation rates ranged from 4.6% to as high as 85% following the placement of IFD/X-STOP devices.^[3,9,10,14] In Kutcha *et al.*'s series, 8 (4.6%) of 175 patients receiving the X-STOP later required device removal with microsurgical decompressions.^[10] In Veerhoof *et al.*'s series, 12 patients with spinal stenosis and grade I spondylolisthesis received X-STOP devices.^[14] These devices were implanted at one level in 10 patients and at two levels in 2 patients. Second operations consisting of decompressions with posterolateral fusions were required in 7 (58%) patients within two postoperative years.^[14] Reoperation rates for IFD devices in two other IFD series ranged from 6% (3 of 50 cases utilizing 34 X-STOP titanium, 8 X-STOP PEEK, and 8 Lanx Aspen)^[9] to 85% (11 of 13 cases utilizing X-STOP),^[3] requiring device removal and laminectomy.^[3,9]

Poor outcomes of interspinous fusion devices

Poor outcomes, defined by recurrent pain, were observed in from 66.7–77% of cases.^[3,5,10,14] Specifically, in Bowers *et al.*'s study, X-STOP devices were implanted in 13 patients; pain initially improved in 72% of patients, but recurred in 77%.^[3] In Brussee *et al.*'s series, in 65 patients treated with the X-STOP devices (averaging 64.4 years of age), 68.9% exhibited poor outcomes.^[4] Poor results best

correlated with multiple comorbid factors and female gender, but not with smoking, elevated body mass index (BMI), or the number of devices utilized/case.

LIMITED UTILITY OF X-STOP WITH SCOLIOSIS

In Rolfe *et al.*'s study involving 179 consecutive patients, higher degrees of scoliosis correlated with poorer outcomes following the placement of X-STOP devices.^[12] Patients were divided into three operative groups: Group 1 (116 control patients) had neurogenic claudication without scoliosis, Group 2 (41 patients) had 11–24 degrees of scoliosis, while Group 3 (22 patients) had high-grade scoliosis (over 25 degrees). Success, defined as improvement of over 15 points on the Oswestry Disability Index, was demonstrated in 56% of patients in Groups 1 and 2, while Group 3 patients with high-grade scoliosis did well only 18% of the time. The authors concluded that X-STOP devices were more effective in those without scoliosis and/or with lesser degrees of scoliosis.

COST-EFFECTIVENESS OF X-STOP

Burnett, Stein, and Bartels performed a structured literature review of conservative treatment, decompressive laminectomy, and X-STOP placement in patients with lumbar stenosis, utilizing quality-adjusted life years along with costs at 2 years following surgery.^[5] They found that laminectomy was the most cost-effective treatment strategy.

At our institution in 2010, involving 16 patients averaging 71 years of age, 7 males and 9 females received 31 X-STOP devices. Four surgeons implanted these devices at from one to three levels; seven patients had one-level devices, three patients had two-level devices, and six patients had three-level devices (not FDA approved) implanted [Table 1]. The average charge for X-STOP devices ranged from \$17,600 for one-level procedures to \$57,201 for three-level procedures. The total charge for implanting all 31 X-STOP devices was \$576,407. Additionally, the total charge for the operating room/recovery room in 16 patients was \$80,944; the average operating room charge/case was \$3908 (average time 2.1 hours) and the average recovery room charge was \$1151/case (average of 4.6 hours) [Table 1].

CONCLUSION

Within up to four postoperative years, IFD devices, including the X-STOP, utilized to treat lumbar stenosis in patients over 50 years of age resulted in up to a 38% complication rate, up to an 85% reoperation rate, and up to a 77% incidence of poor outcomes.^[1,3,5,9,10,14] Regarding outcomes, the limited “efficacy” of the X-STOP device

Table 1: Charges of 16 X-STOP devices placed in 31 patients at a single institution in 2010

Variable	Data (16 patients)
Age (years)	
Average	71
Range	47–80
Sex	
Males	7
Females	9
Total X-STOP devices	31
One level	7
Two levels	3
Three levels	6
Operating room time (hours)	
Average	2.1
Range	1.5–3.0
Operating room charges	
Average	\$3908
Range	\$3202–\$4989

was best summarized by Medtronic on their own website (Medtronic, Memphis, TN, USA: X STOP[R] IPD[R] System Summary of Safety and Effectiveness, 2005). They state thus: “Although many patients benefit from the use of this treatment, approximately half of the patients who received the X-STOP device in the 2-year study experience a degree of pain relief and ability to increase their activity levels that was sufficient to be considered a successful outcome at 2 years after surgery.” Consider also the total \$576,407 charge for 31 IFD devices (X-STOP) implanted in 16 patients at one institution in 2010, plus the added \$80,944 charge for the operating room/recovery room. Based upon these data, we, as spine surgeons, should question whether IFD devices should be implanted, as they appear to be neither safe nor effective, and are extremely costly.

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